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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|----------------------|------------------------|------------------|
| 10/664,008 | 09/16/2003 | Benedikt Sas | 4532680/16900 (KEM 69) | 3907 |
| 26386 DAVIS, BROV | 7590 06/11/2007 VN, KOEHN, SHORS & F | EXAMINER | | |
| THE FINANCIAL CENTER 666 WALNUT STREET SUITE 2500 DES MOINES, IA 50309-3993 | | | WANG, SHENGJUN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1617 | |
| | | • | | |
| • | | | MAIL DATE | DELIVERY MODE |
| | | | 06/11/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | Application No. | Applicant(s) | | | | |
|--|---|---|--|--|--|--|--|
| | | 10/664,008 | SAS ET AL. | | | | |
| | Office Action Summary | Examiner | Art Unit | | | | |
| | | Shengjun Wang | 1617 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| WHIC - Exte after - If NC - Failu Any | ORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DANSIONS of time may be available under the provisions of 37 CFR 1.15 SIX (6) MONTHS from the mailing date of this communication. Operiod for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNION (36(a). In no event, however, may a rewritten apply and will expire SIX (6) MON (cause the application to become AB | CATION. eply be timely filed THS from the mailing date of this communication. EANDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | | |
| 1)⊠ | Responsive to communication(s) filed on 19 M | arch 2007. | | | | | |
| 2a)[_ | This action is FINAL . 2b) This action is non-final. | | | | | | |
| 3) | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | | |
| | closed in accordance with the practice under E | x parte Quayle, 1935 C.D | . 11, 453 O.G. 213. | | | | |
| Disposit | ion of Claims | | | | | | |
| | 4) Claim(s) 1-11 is/are pending in the application. | | | | | | |
| | 4a) Of the above claim(s) <u>4</u> is/are withdrawn fro Claim(s) is/are allowed. | om consideration. | | | | | |
| · <u>-</u> | Claim(s) <u>1-3 and 5-11</u> is/are rejected. | | | | | | |
| · — | Claim(s) is/are objected to. | • | | | | | |
| | 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Applicati | ion Papers | | · | | | | |
| 9) | The specification is objected to by the Examine | r. | | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | |
| Priority ι | under 35 U.S.C. § 119 | | | | | | |
| | Acknowledgment is made of a claim for foreign All b) Some * c) None of: | | 119(a)-(d) or (f). | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | | | |
| 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| | | | · · | | | | |
| Attachmen | | | | | | | |
| | e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) | | ummary (PTO-413))/Mail Date | | | | |
| 3) 🛛 Inforr | mation Disclosure Statement(s) (PTO/SB/08) r No(s)/Mail Date | _ | formal Patent Application | | | | |

Application/Control Number: 10/664,008 Page 2

Art Unit: 1617

DETAILED ACTION

1. Claim 4 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 19, 2007.

- 1. Applicant's election without traverse of invention group I, drawn to method of treating Flaviviridae comprising administering a compound defined in claim 1, wherein X1, X2, Y and Z are oxygen, and hepatitis C (HCV) as the elected species of diseases treated in the reply filed on December 4, 2006 and March 19, 2007 is acknowledged. Applicant's election.
- 2. The claims have been examined insofar as they read on the elected invention and species.

Claim Rejections 35 U.S.C. 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 4. Claims 1-3, 5-11 rejected under 35 U.S.C. 103(a) as being unpatentable over Qian et al. (J. Traditional Chinese Medicine vol. 2, No. 4, pp 272-276), Efferth et al. (IDS), Zheng et al. (IDS), Venugopalan et al. (EP 0 456 149 A1, IDS), and Li et al. (CN 1122806 A), and in further view of Crooks et al. (US 6,677,347).
- 5. Qian et al. teaches that artemisinin (qinghaosu) have immunologic and antiviral activity. It augments cell-mediated immunity. See, particularly the Abstract. Efferth et al. teaches that

Art Unit: 1617

artesunate is effective against cytomegalovirus, see, particularly the abstract; Zheng et al. also teaches that artemether is effective for suppressing the epidemic hemorrhagic fever virus. See, particularly, the abstract. Venugopalan et al. teaches method of treating viral infection comprising administering artemisinin compounds. See, particularly the claims. Li et al. teaches artemisinin derivatives are known to be useful as anti-tumor, antiviral and anti-parasitic agents. See, particularly the abstract. It is noted that the artemisinin derivatives employed by Venugopalan et al and Li et al. is not within the scope of artemisinin compounds defined herein, but, the compounds all have the core structure of artemisinin. The cited references as a whole have fairly teach or suggest that compounds with the core structure of artemisinin have a broad spectrum of antiviral, anti-tumor, anti-parasitic activity and have immunologic augmenting activity.

- 6. The prima references as a whole do not teach expressly the employment of the artemisinin compounds for treatment of hepatitis C infection, alone, or with interferon.
- 7. However, Crooks et al. teaches that compound that augments cell-mediated immunity, as well as interferon, are useful for treatment of tumors and viral infections, such as hepatitis C infection. See, particularly, col. 19, line 39 to col. 20, line 54.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ artemisinin, alone, or with interferon, for the treatment of hepatitis C infection.

A person of ordinary skill in the art would have been motivated to employ artemisinin, alone, or with interferon, for the treatment of hepatitis C infection because artemisinin are antiviral agents useful against a broad spectrum of virus and are known to augment cell-mediated

Art Unit: 1617

immunity and compounds augmenting cell-mediated immunity, as well as interferon, are useful for treating viral infections, such as hepatitis C infection. The further employment of interferon with artemisinin would have been obvious because both agents are known to be useful for treatment of viral infections and it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, the claimed invention which is a combination of two known antiviral agents sets forth prima facie obvious subject matter. See In re Kerkhoven, 205 USPQ 1069.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/664,008

Art Unit: 1617

SHENGJUN WANG

Shengjun Wang Primary Examiner Art Unit 1617